DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

GS197d

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-05-18

February 1, 2005

Hans Katros, Operating Manager
Katros Groves/Citrus Direct
1053 Biltmore Drive NW
Winter Haven, Florida 33881

Dear Mr. Katros:

The U.S. Food and Drug Administration (FDA) inspected your firm, located at 8043 Lake Lowry Road, Haines City, Florida, 33844, on August 6 and 10, 2004. We found that you have serious deviations from the Juice HACCP Regulation (21 CFR 120) and the Current Good Manufacturing Practices (GMP) regulation for foods (21 CFR Part 110). In accordance with 21 CFR 120.9, failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part renders the juice products **adulterated** within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your fresh orange juice, fresh grapefruit juice, fresh lemon juice, and fresh lime juice are adulterated, in that the products were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

You can find the Act and the Juice HACCP regulation through links in FDA's homepage at http:// www.fda.gov.

The significant deviations were as follows:

1. You must have records documenting verification of your Hazard Analysis Critical Control Point (HACCP) system to comply with 21 CFR 120.12(a)(5). However, when requested by our investigator, your firm was unable to provide the required records. 21 CFR 120.11(a) requires each processor to verify that the Hazard Analysis and Critical Control Point (HACCP) system is being implemented according to design. As a processor of citrus juice that relies in whole or in part on surface treatment of fruit, your firm is required by 21 CFR 120.11(a)(1)((iii) to perform end-product testing in accordance with all the requirements specified in 21 CFR 120.25.

2. You must have records documenting the implementation of the sanitation standard operating procedures (SSOP's), a written Hazard Analysis, a written HACCP plan, and critical control point monitoring records documenting the ongoing application of your HACCP plan as they apply to your Hazard Analysis Critical Control Point (HACCP) system to comply with 21 CFR 120.12(a)(1), (2), (3) and (4). However, when requested by our investigator, your firm was unable to provide records documenting the implementation of the sanitation standard operating procedures (SSOP's), a written Hazard Analysis for all of your products, or a written HACCP plan for fresh lime juice and fresh lemon juice. In addition, when requested by our investigator, your firm was unable to provide records documenting the monitoring of critical control points and their critical limits for your fresh orange juice and grapefruit juice.

3. You must have a written HACCP plan that lists monitoring procedures and the frequency with which they are to be performed for each critical control point, to comply with 21 CFR 120.8(b)(4). However, your firm's HACCP plan for "Fresh Orange Juice, Grapefruit Juice" lists monitoring procedures that are not adequate at the "First Brush Washing," "Secondary Brush Washing," and "Hot Water Brushing" critical control points. Specifically, your firm's monitoring procedures are incomplete in that they do not address the parameters of time established in your critical limits.

4. You must monitor conditions and practices during processing with sufficient frequency to ensure conformance with the Current Good Manufacturing Practice regulation, to comply with 21 CFR 120.6(b). However, your firm did not monitor the safety of water; the condition and cleanliness of food contact surfaces; prevention of cross-contamination from insanitary objects; the proper labeling, storage, and use of toxic compounds; and the exclusion of pests with sufficient frequency, as evidenced by:

    - Leaking well unit with an accumulation of rust on the front, an orange/brown residue on the outside case of the filtration units, and a mold-like residue along the seal of the unit and the cartridge.
    - Badly cracked belts on the fruit washing equipment and presence of mold-like residue on the food contact surfaces of the [redacted] extractor, fruit washer, and water spray jets.
    - Hoses used to transport raw juice were noted lying directly on floors of the facility, which were observed as having standing water and mold-like residue; finished product was observed coming in direct contact with equipment having a mold-like residue; and a dog was observed in the facility, including in the processing area.
    - Gasoline, pesticides, chlorine and chemicals stored with food items, including sugar and raw oranges.
    - Numerous flies in the processing area that were also landing on equipment, unused equipment and other items littered in the area around the firm, and an inadequate disposal of trash and waste materials.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. You may wish to include in your response documentation such as amended HACCP plans, revised forms, or other useful information that would assist us in evaluating your corrections. If you are unable to complete all of the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Juice HACCP Regulation, and the Current Good Manufacturing Practice Regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U. S. Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,

Emma R. Singleton
Director, Florida District